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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/901,938 | 07/10/2001 | Michael Econs | 053884-5001 | 9281 |
| 28977 | 7590 | 05/05/2004 | EXAMINER | |
| MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921 | | | SAUD, CHRISTINE J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,938

Applicant(s)

ECONS ET AL.

Examiner

Christine J. Saoud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) 17-31, 34, 35, 39-42 and 44-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-11, 32, 38, 43 and 83 is/are allowed.
- 6) ☐ Claim(s) 12 and 33 is/are rejected.
- 7) ☐ Claim(s) 13-16, 36-37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/30/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

At page 16 of the response, Applicant requests consideration of claims 22-24, 80, 82 and 83. Applicant is reminded that the election of the invention for prosecution was made without traverse. However, upon reviewing the instant claims, it would be appropriate to include claims 24 and 83 in the current examination. Claims 22-23, 80 and 82 would require new grounds of rejection which would preclude making the instant Office Action final, as well as requiring further search and consideration. Claims 17-23, 25-31, 34-35, 39-42, 44-79, 80-82 remain withdrawn as being drawn to a nonelected invention, said election made without traverse in Paper No. 8.

Applicant argues the withdrawal of claims 22-24, 80, 82 and 83 and asserts that there is no burden of search associated with searching "mutants". This assertion is not correct, because, for example, claim 22 is a claim that requires no structure whatsoever, wherein the nucleic acid comprises a mutation. The search of this claim goes way beyond any sort of sequence similarity to the elected SEQ ID NO:1, but encompasses nucleic acids which encode any protein which could be construed as and FGF-23 and also comprises a mutation. This may conceivably encompass FGF-22 or FGF-24 or FGF-12, etc. because who is to say that related proteins did not arise from mutations? Therefore, the search and examination of these claims goes well beyond the scope of the elected invention and creates a burden of search, absent evidence to the contrary.

Claim Rejections - 35 USC § 112

Claims 12 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the previous Office action, claims 1-4, 7, 12 and 43 were rejected as being indefinite. The use of the recitation "fibroblast growth factor-23 (FGF23)" with no further description was indicated to be indefinite (claim 1). By typographical error, claim 12 was not indicated to have this issue, even though it is clear from the claims that this is the same problem as was pointed out for claim 1. In response to this ground of rejection for claim 1, Applicant has amended claim 1 to include SEQ ID NO:1. Claim 12 is still indefinite for the recitation of "fibroblast growth factor-23 (FGF23)" and this is not considered a new ground of rejection because the issue was clearly indicated in the previous Office action and Applicant acknowledged the issue and avoided it by amendment of claim 1. This rejection can also be avoided by amendment.

Claim 33 is indefinite because it depends from an indefinite claim, claim 12.

Claim Objections

Claims 13-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 36-37, in so far as they encompass non-elected subject matter (i.e. FGF-23 molecules not related to SEQ ID NO:1) are objected to. Furthermore, these claims depend from non-elected claims, and therefore, are objected to.

Allowable Subject Matter

Claims 1-11, 24, 32, 38, 43, 83 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

Art Unit: 1647

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


CHRISTINE J. SAOUD
PRIMARY EXAMINER

CHRISTINE J. SAOUD
PRIMARY EXAMINER
